

CLAIMS:

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1. An isolated antigenic peptide comprising an amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14 that induces an anti-IgE immune response that does not cause anaphylaxis when administered to an animal.
 2. An isolated antigenic fusion protein comprising an amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14 that induces an anti-IgE immune response that does not cause anaphylaxis when administered to an animal.
 3. An isolated polynucleotide sequence encoding an antigenic peptide comprising an amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14, wherein said antigenic peptide inducing an anti-IgE immune response that does not cause anaphylaxis when administered to an animal.
 4. An isolated polynucleotide sequence encoding an antigenic fusion protein comprising an amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14, wherein said antigenic fusion protein inducing an anti-IgE immune response that does not cause anaphylaxis when administered to an animal.
 5. A genetically engineered host cell that contains the polynucleotide sequence of claim 3 or 4.
 6. A genetically engineered host cell that contains the polynucleotide sequence of claim 3 or 4 in operative association with a nucleotide regulatory sequence that controls expression of the polynucleotide sequence in the host cell.
 7. A pharmaceutical composition for inducing an anti-IgE immune response that does not cause anaphylaxis comprising one or more antigenic peptides having an amino acid sequence comprising amino acid residues of a CH3 domain of an IgE molecule or a fragment thereof.
 8. The pharmaceutical composition of claim 7, wherein at least one antigenic peptide has the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14.

9. A pharmaceutical composition for inducing an anti-IgE immune response that does not cause anaphylaxis comprising one or more antigenic fusion proteins having an amino acid sequence comprising amino acid residues of a CH3 domain of an IgE molecule or a fragment thereof and a heterologous carrier protein.

5 10. The pharmaceutical composition of claim 9, wherein at least one antigenic fusion protein has the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14.

11. The pharmaceutical composition of claim 9, wherein the heterologous carrier 10 protein is selected from the group consisting of KLh, PhoE, rmLT, TraT, and gD from BhV-1 virus.

15 12. The pharmaceutical composition of claim 7 or 9, wherein the anti-IgE immune response is the production of anti-IgE antibodies which bind to soluble IgE in serum and other bodily fluids, prevent IgE from binding to its high affinity receptors on mast cells and basophils, and do not cross-link receptor-bound IgE.

13. The pharmaceutical composition of claim 7 or 9 further comprising an adjuvant.

20 14. A pharmaceutical composition for inducing an anti-IgE immune response that does not cause anaphylaxis comprising one or more polynucleotide sequences encoding an antigenic peptide having an amino acid sequence comprising amino acid residues of a CH3 domain of an IgE molecule or a fragment thereof.

25 15. The pharmaceutical composition of claim 14, wherein at least one polynucleotide sequence encodes an antigenic peptide having the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14.

30 16. A pharmaceutical composition for inducing an anti-IgE immune response that does not cause anaphylaxis comprising one or more polynucleotide sequences encoding an antigenic fusion protein having an amino acid sequence comprising amino acid residues of a CH3 domain of an IgE molecule or a fragment thereof and a heterologous carrier protein.

35 17. The pharmaceutical composition of claim 16, wherein at least one polynucleotide sequence encodes an antigenic fusion protein having the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14

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18. The pharmaceutical composition of claim 16, wherein the heterologous carrier protein is selected from the group consisting of KLh, PhoE, rmLT, TraT, and gD from BhV-1 virus.

19. A method for the treating or preventing an IgE-mediated allergic disorder comprising administering to an animal in which such treatment or prevention is desired a immunogenically effective amount of one or more antigenic peptides having an amino acid sequence comprising amino acid residues of a CH3 domain of an IgE molecule or a fragment thereof.

20. The method of claim 19, wherein at least one antigenic peptide has the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14.

21. A method for the treating or preventing an IgE-mediated allergic disorder comprising administering to an animal in which such treatment or prevention is desired a immunogenically effective amount of one or more antigenic fusion protein having an amino acid sequence comprising amino acid residues of a CH3 domain of an IgE molecule or a fragment thereof and a heterologous carrier protein.

22. The method of claim 21, wherein at least one antigenic peptide has the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14.

23. A method for the treating or preventing an IgE-mediated allergic disorder comprising administering to an animal in which such treatment or prevention is desired a immunogenically effective amount of one or more polynucleotide sequences encoding one or more antigenic peptides having an amino acid sequence comprising amino acid residues of a CH3 domain of an IgE molecule or a fragment thereof.

24. The method of claim 23, wherein at least one antigenic peptide has the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14.

25. A method for the treating or preventing an IgE-mediated allergic disorder comprising administering to an animal in which such treatment or prevention is desired a immunogenically effective amount of one or more polynucleotide sequences encoding one or more antigenic fusion proteins having an amino acid sequence comprising amino acid residues of a CH3 domain of an IgE molecule or a fragment thereof and a heterologous carrier protein.

26. The method of claim 25, wherein at least one antigenic peptide has the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, or SEQ ID NO: 14.
- 5 27. The method of claim 19, 21, 23 or 25 in which the animal is human.
28. The method of claim 19, 20, 21, 22, 23, 24, 25 or 26 in which the animal is a dog.
- 10 29. The method of claim 19, 20, 21, 22, 23, 24, 25 or 26, wherein the IgE-mediated allergic disorder is asthma, allergic rhinitis, gastrointestinal allergies such as food allergies, eosinophilia, conjunctivitis, or glomerular nephritis.
30. An isolated polynucleotide sequence comprising the polynucleotide sequence of SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, or SEQ ID NO: 21.
- 15 31. An isolated polynucleotide sequence comprising the polynucleotide sequence of SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26 SEQ ID NO: 27, or SEQ ID NO: 28.
- 20 32. A method for evaluating the effect of anti-IgE vaccines in dogs which comprises sensitization of the dogs to an allergen by concurrent administration of the allergen and ricin in amounts sufficient to induce hypersensitivity in the dogs, followed by challenge with the allergen and observation of the resulting sensitivity of the dogs to the challenge allergen.
- 25 33. A method for inducing high levels of IgE and clinical signs of hypersensitivity in dogs for evaluating the effect of anti-IgE vaccines in the dogs which comprises: sensitization of the dogs to an allergen sufficient to induce hypersensitivity in the dogs by concurrent administration of amounts of the allergen and ricin sufficient to the dogs, followed by challenge with the allergen and observation of the resulting sensitivity of the dogs to the challenge allergen.
- 30 34. The method of claim 32 or 33 wherein the allergen is a flea allergen.
35. The method of claim 32 or 33 wherein the allergen is a food allergen.
36. The method of claim 32 or 33 wherein the food allergen is an ascaris allergen.
37. The method of claim 32 or 33 wherein the hypersensitivity is type I hypersensitivity.
38. The method of claim 32 or 33 wherein sensitization results in higher levels of IgE in the hypersensitized dogs than found in non-hypersensitized dogs.
39. An isolated antigenic peptide comprising an amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID



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** CONTINUING DATA *****

THIS APPLN CLAIMS BENEFIT OF 60/228,989 08/30/2000 *OK, PNH*

** FOREIGN APPLICATIONS *****

None, PNH

IF REQUIRED, FOREIGN FILING LICENSE GRANTED

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TOTAL CLAIMS	TOTAL CLAIMS 41
INDEPENDENT CLAIMS	INDEPENDENT CLAIMS 18

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TITLE

Anti-IgE vaccines

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